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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,937

10/31/2006

Michael R. Costa

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,937	Applicant(s) COSTA ET AL.	
	Examiner KAGNEW H. GEBREYESUS	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2-7 and 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8-12, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The notice of abandonment mailed on April, 17, 2008 has been vacated in favor of the instant Office action.

Applicant's election of the invention in Group II comprising claims 1, 8-12, 16-19 drawn to a method of identifying a test agent that modulates PTEN pathway through interference with a nucleic acid encoding microtubule affinity regulating kinase (MARK) dated April 14, 2008 is acknowledged. Claims 2-7, 13-15, 20-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected groups, there being no allowable or linking claims.

Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Status of the claims

Claims 1-25 are pending. Claims 2-7, 13-15, 20-25 are withdrawn for pertaining to nonelected subject matter. **Claims** 1, 8-12, 16-19 are presently under examination.

Priority

Priority for this application is acknowledged for benefit of U.S. Provisional Application No. 60/479,768, filed on June 19, 2003.

Information Disclosure Statement

The information disclosure statement filed on November 20, 2006 for which a

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copy of the patent publication has been submitted in this application has been considered as shown by the Examiners signature next to each reference.

Oath/Declaration

The oath or declaration using an Application data sheet submitted on October 31, 2006 has been reviewed and is in compliance with 37 CFR 1.63.

Claim Objections

Claims 1, 8-12, 16-19 are objected to because of the abbreviations PTEN, MARK or PMO. Abbreviations must be written out in full in the first instance of their appearance. In the first instance of their appearance, the term "PTEN" should be written as "phosphatase and tensin homolog deleted on chromosome ten (PTEN)", MARK should be written as "microtubule affinity regulating kinase (MARK)" and PMO should be written as "phosphothioate morpholino oligomer (PMO)".

Claims 1, 8-12, 16-19 are objected to for comprising non-elected subject groups. The elected group encompasses a method of identifying non-elected subject matter i.e. MAP kinase polypeptide inhibitors. Appropriate amendment is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8-12, 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Furthermore claims 16-19 are rejected for the recitation "...secondary assay system...". It is unclear what kind of assay is encompassed in these claims. The metes and bounds of this recitation are indefinite.

Furthermore, the recitation "...the test agent or agent derived therefrom..." is indefinite. It is not clear how one of skill can distinguish between a derivative of a test agent and the agent because the nature of the test agent itself is not defined. Clarification of the claims is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-12, 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is

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claimed.” In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention.

These claims are directed to a method of identifying an agent that modulates PTEN pathway comprising an assay that uses a genus of MARK nucleic acids from any source. The specification describes the structure of a few MARK kinases, SEQ ID NO: 5, 8 and 10 comprising 4726 nucleotides, 1725 nucleotides or 4919 nucleotides respectively. Thus various structurally unrelated MARK polynucleotide structures are encompassed. However, the specification does not describe an identifying characteristic or property for the structure of all possible MARK polynucleotides other than the functionality of being a MARK polynucleotides. The specification does not teach using any MARK polynucleotide with any structure in the assay system to identify a candidate PTEN pathway modulating agent.

The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. Eli Lilly, 119 F.3d at 1567, 43 USPQ2d at 1405. Compare Fonar Corp. v. General Electric Co., 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997).

Thus to satisfy the written description requirement for the claimed genus of MARK polynucleotides to be used in the assay system, a sufficient description of a representative number of species by actual reduction to practice, or by a disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical

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properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus must be provided (*See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406*).

In the instant case, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides.

Furthermore the specification does not describe how PTEN, a dual specificity protein phosphatase and a lipid phosphatase which dephosphorylates the phospholipid PIP₃ and thus modulates the activity of downstream signaling pathways such as activity of AKT relates to polynucleotide encoding MARK.

In addition, the specification does not describe how the function of a defective PTEN can be overcome by expressing a recombinant polynucleotide encoding a MARK polypeptide.

Given that the specification lacks description for a link between a polynucleotide encoding a MARK polypeptide and PTEN pathway, the specification fails to describe the claimed invention in a clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Drewes et al. (MARK, a Novel Family of Protein Kinases That Phosphorylate a Microtubule Associated protein and Trigger Microtubule Disruption Cell vol. 89, 297-308, 1997). Drewes et al teach an assay wherein CHO cells were transformed with a vector comprising a polynucleotide that encodes MARK in cells in the presence or in the absence of taxotere, an agent that stabilizes microtubules. Furthermore they teach an assay wherein a polynucleotide that encodes MARK was co-transformed with a vector expressing MAP2c. In both of the above assays, differential phenotypes of CHO cells were seen (see Drewes et al page 303, fig. 5). Claims 1, 8, 11, 16 and 17 encompass a method comprising a polynucleotide encoding a MARK kinase in cells in the presence of a test agent (taxotere or the MAP2c) and detecting a test agent biased activity. Fig. 5 on page 303 shows this test agent biased activity in the form of a phenotypic change of the cells, thus these claims are anticipated.

Conclusion: No claims are allowed.

Relevant publication(s):

Phosphorylation of MAP2c and MAP4 by MARK kinases leads to the Destabilization of Microtubules in cells. Drewes et al in Cell Motility and the cytoskeleton. Vol. 44:209-224, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew H Gebreyesus PhD
Examiner
Art Unit 1656

/Robert B Mondesi/
Primary Examiner, Art Unit 1652